

REMARKS

The present invention provides, *inter alia*, for a self-adhering plaster applied to the skin having a first “core” adhesive containing an active pharmaceutical drug compound surrounded by a second “ring” adhesive having lower flowability than the core adhesive to prevent the core adhesive from flowing outside of the ring adhesive. Because the ring adhesive has increased stickiness, *i.e.* lower flowability, as compared with the core adhesive, the core adhesive is precluded from flowing beyond the ring adhesive.

Claims 1-8 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,538,736 to Hoffmann et al. (“Hoffmann”). The Office Action asserts that “Hoffmann disclose an active-substance containing plaster for the controlled release of active substances to the skin comprising two different adhesives, each with distinct flowable adhesion properties.” (Office Action at 2). This rejection is respectfully traversed.

The presented claims provide a plaster having reduced cold flow. Reduced cold flow is achieved by surrounding the core adhesive containing the active pharmaceutical ingredient with an adhesive having lower flowability than the core adhesive. Plasters of the prior art comprise an adhesive containing an active pharmaceutical compound that can “flow” and escape the patch and adhere to the packaging material during storage or adhere to the surrounding clothing or other articles which are in contact to the skin during the duration of application to the skin. The result is “dirty fringe”. Dirty fringe is detrimental to the appearance of the adhesive. The present invention overcomes this problem.

It has been surprisingly found that a plaster comprising the novel combination of a core adhesive containing an active pharmaceutical compound surrounded by a ring adhesive having a lower flowability, *i.e.*, an increase in stickiness, is capable of preventing the core adhesive from escaping the boundaries of the patch and thus, prevent dirty fringe.

Claim 1 of the present application includes the limitation “a layer adhesive which attaches to skin having a core of adhesive which is a flowable adhesive and a ring of adhesive being an adhesive having reduced flowability to that of the core . . .” In other words, claim 1 is directed to a plaster containing two different adhesives applied to the skin having different flowability.

It is respectfully urged that Hoffmann does not disclose or suggest each and every element of the present invention, as claimed, and reconsideration and withdrawal of this rejection is requested because Hoffmann does not disclose or suggest a core adhesive surrounded by a ring adhesive having lower flowability. Furthermore, Hoffmann does not address, or solve, the problem of dirty fringe.

Hoffmann does not provide for “active substances applied to the skin comprising two different adhesives, each with distinct flowable adhesion properties”.

In contrast to the present invention, Hoffmann provides a peel-off layer that is able to remain attached to one of two reservoirs containing active ingredient when a back layer which encloses the entire patch is removed:

The system has at least two drug reservoirs, a first and second reservoir. The second reservoir is removed and the first remains attached to the skin[sic]. This is accomplished by the use of a peel-off layer which covers the back of the first reservoir, which is made of an essentially nonsticky material. A back layer, which covers and encloses the entire patch rests on top of the peel-off layer and the peel-off layer adheres to the first

reservoir. When the back layer is removed, the second reservoir is lifted off the skin, but since the peel-off layer does not adhere to the back layer the first reservoir remains and adheres to the skin.

(Hoffmann at col. 3, lines 4-15.)

Specifically, Hoffmann discloses that the adhesion level between the peel-off layer and the back layer is different than the adhesion level between the peel-off layer and the reservoir:

The skin side adhesive layers 21,22 on the non-adhesive active substance reservoir parts 24,25 are so adjusted that the adhesion of the adhesive layer 22 of the first active substance reservoir part 24 to the skin is greater than the adhesion between the peel-off layer 26 and the adhesive layer 27[adhesive layer 27 is fixed between the back layer and the peel off layer].

(Hoffmann at col. 5, lines 35-39).

Hence, Hoffmann provides that one of the active substance reservoirs can be removed with the back layer, leaving the other reservoir onto the skin. This does not reflect that both reservoirs, *i.e.*, reservoir materials, have different tackiness. Indeed, the opposite applies, one of the reservoirs is separated from the back layer by a peel-off layer and it is this peel-off layer that has a reduced stickiness to the back layer as compared with the other reservoir and the back layer.

Furthermore, Hoffmann does not prescribe that the two reservoirs comprise different adhesive materials anywhere in the specification. On the contrary, Hoffman provides that the reservoirs have the same adhesion to the skin because a uniform protective layer must be removed simultaneously from the skin-side active substance reservoirs before applying the plaster to the skin. (Hoffmann at col. 5, lines 3-4).

Thus, Hoffmann does not provide for different levels of stickiness from the adhesives applied to the skin. Instead, Hoffmann discloses a the peel-off layer that does

not stick to the back layer so that one of the reservoirs may be removed without disturbing the other.

The skilled person reading Hoffmann is therefore directed towards the use of adhesives containing the active pharmaceutical ingredient having the same flowability. Hoffmann does not provide the use of adhesives having different flowability to prevent the escape of the active pharmaceutical compound. Thus, claims 1-8 are novel over the Hoffmann

With respect to the Section 102 rejection, the Examiner is respectfully reminded that anticipation requires that each and every element of the claimed invention be disclosed in a single prior art reference. *In re Spada*, 15 USPQ2d 1655 (Fed. Cir. 1990). For anticipation, there must be no difference between the claimed invention and the reference disclosure. *Scripps Clinic & Res. Found. v. Genetech, Inc.*, 18 USPQ2d 1001 (Fed. Cir. 1988). Exact identity is required.

Accordingly, it is respectfully submitted Hoffmann does not mention, disclose or suggest the recitation “a layer adhesive which attaches to skin having a core of adhesive which is a flowable adhesive and a ring of adhesive being an adhesive having reduced flowability to that of the core . . .”

Or, more generally, there is no suggestion in Hoffmann that a plaster comprising adhesives applied to the skin having different flowability.

Thus, claims 1-8, which is directed to a core adhesive surrounded by ring adhesive with different flowability, is novel over Hoffmann.

Accordingly, it is submitted that the claims as presented are distinct from the art cited and a notice of allowance is therefore requested.

REQUEST FOR INTERVIEW

If any issue remains as an impediment to allowance, an interview with the Examiner is respectfully requested, prior to issuance of any paper other than a Notice of Allowance; and, the Examiner is respectfully requested to contact the undersigned to arrange a mutually convenient time and manner for such an interview.

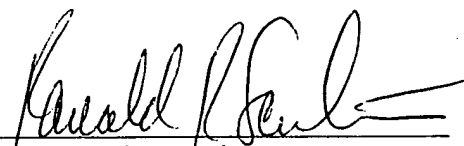
CONCLUSION

In view of the remarks herewith and those of record, the application is in condition for allowance. Favorable reconsideration of the application and prompt issuance of a Notice of Allowance, or an interview at a very early date with a view to placing the application in condition for allowance, are earnestly solicited. The undersigned looks forward to hearing favorably from the Examiner at an early date.

The Commissioner is authorized to charge any additional fees that may be required to Deposit Account No. 50-0320.

Respectfully submitted,

FROMMER LAWRENCE & HAUG LLP
Attorneys for Applicant

By: 
Ronald R. Santucci
Reg. No. 28,988
Tel. (212) 588-0800